



DEPARTMENT OF HEALTH & HUMAN SERVICES

Substance Abuse and Mental
Health Services Administration

Center for Mental Health Services
Center for Substance Abuse
Prevention
Center for Substance Abuse
Treatment
Rockville MD 20857

MAR 6 2001

Dear Colleague:

On January 17, the Federal Register published the Final Rule pertaining to the use of methadone and levo-alpha-acetyl-methadol (LAAM) in the treatment of opioid dependence (enclosure). The effective date of the Final Rule was established as 60 days from the date of publication, i.e., March 19. On January 20, the President issued a directive requiring a regulatory review plan that extended the effective date for all Federal regulations, including this one, for an additional 60-day period. We have determined that the impact of this policy is to move the effective date for this Final Rule to May 18. A Federal Register notice was issued to announce the new date (enclosure).

This Final Rule replaces the current Food and Drug Administration (FDA) inspection-focused "methadone regulations" with a certification program that will be administered by the Substance Abuse and Mental Health Services Administration and the Center for Substance Abuse Treatment (CSAT). CSAT has assembled a variety of materials, including the Final Rule, to introduce the new Federal regulatory requirements to you and your staff, to address many of your questions about the certification and accreditation process, and to alert you to the schedule for its implementation. The Final Rule does not affect any regulatory requirements of the Drug Enforcement Administration (DEA) with respect to opioid treatment programs (OTPs).

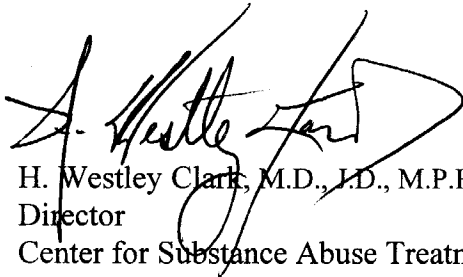
Over the past several years, numerous OTP medical and clinical staff, patients, and administrators have worked with CSAT, FDA, and DEA to develop a comprehensive certification program that enhances the field's flexibility, accountability, and capacity in response to patient needs. The certification and accreditation process defined in the Final Rule will provide a framework for attaining those crucial objectives. Under the Final Rule, CSAT will approve a number of accrediting bodies to conduct onsite reviews of OTPs that are designed to assess program quality and functioning as measured against the Federal Opioid Treatment Standards.

We hope the enclosed materials will address many of your most immediate questions. CSAT is planning to convene a series of technical assistance workshops around the country to provide you and others an opportunity to meet with CSAT staff to discuss and clarify any outstanding issues with respect to the requirements of the Final Rule. In addition, we will learn from the experiences of OTPs that have successfully undergone the accreditation process, and will describe the assistance available to you throughout the certification process. We have enclosed information about these upcoming technical assistance workshops.

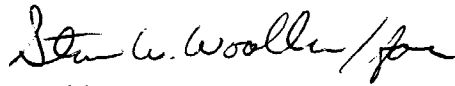
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Publication of the Final Rule represents the culmination of a successful partnership between CSAT, FDA, and the members of the OTP community. We look forward to continuing that positive collaboration as we take this first, critical step to implement the OTP certification process. For immediate questions about the Final Rule, please contact Mr. Robert Lubran, Acting Director, Office of Pharmacologic and Alternative Therapies, CSAT, at (301) 443-0744.

Sincerely,



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Director
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Enclosures